

airway over time and substantially prevents regrowth.” (emphasis supplied). The application therefore clearly supports treating or irradiating smooth muscle tissue at an intensity that, over time, causes a reduction in bulk (debulking) and prevents regrowth. The application at page 11, lines 6-7, also indicates that the present invention can be used to “debulk” enlarged smooth muscle tissue instead of eliminating the smooth muscle tissue altogether. No new matter has been introduced by the above amendment.

## **II. REMARKS**

Claims 28-47, 50, and 51 have been examined and stand rejected on various grounds. These objections and rejections are addressed in the sections below.

Claims 1-27, 48 and 49 have been withdrawn from consideration by the Office pursuant to an election/restriction requirement. Applicant expressly reserves his right to file one or more applications directed to the same or similar subject matter under 35 U.S.C. §120.

In view of the preceding amendments and the remarks made herein, the present application is believed to be in condition for allowance.

### **35 U.S.C. § 112, Second Paragraph**

Claims 28-32, 34, 35, 39, 40, 44, and 45 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended claims 28-32, 34, 35, 39, 40, 44, and 45 and submit these claims are not indefinite for failing to recite how they “manipulatively” affect the method. The standard for indefiniteness under 35 U.S.C. § 112, second paragraph, is whether one of ordinary skill in the art would understand the claim’s scope when viewed in light of the specification. *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1378 (Fed. Cir. 1999). Accordingly, the test for indefiniteness under Section 112 is not based on whether the dependent claims

“manipulate” the method, but whether one of ordinary skill in the art would understand the claim’s scope when viewed in light of the specification.

Upon review of the claims at issue, it is clear that each claim limitation limits the scope of the claim and thus appries one of ordinary skill in the art what subject matter is covered by the claim. In particular, claim 28 has been amended to point out how the irradiating step is performed. Claims 29, 34, 39, and 44 also further limit the irradiating step. In particular, claims 29, 34, 39, and 44 limit the irradiating step to use light energy in the range of 240 to 280 nm. Regarding claims 30, 35, 40, and 45, each requires the irradiating step to use light energy in the red visible range. Thus, the scope of these claims is indeed limited and should be clear to one of ordinary skill in the art.

Based on the foregoing, Applicant submits all the claims meet the requirements of Section 112, paragraph 2. It is respectfully requested that the rejections of claims 28-32, 34, 35, 39, 40, 44, and 45 under Section 112, second paragraph, be withdrawn.

### **35 U.S.C. § 102(b)**

Claims 33, 37, 50, and 51 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dierkesmann.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *See* MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631(Fed. Cir. 1987)).

In this case, Dierkesmann fails to describe each of the elements required in claims 33, 37, 50, and 51. In particular, Dierkesmann does not describe Applicant’s claimed step of irradiating the walls with an intensity and wavelength sufficient to cause, over time, debulking of the tissue. Support in Applicant’s specification for irradiating the walls with an intensity and wavelength sufficient to cause, over time, debulking or shrinkage of the tissue can be found at page 6, lines 12-22. Dierkesmann teaches neither of these limitations.

In contrast, Dierkesmann describes destroying and vaporizing targets such as obstructing lesions. (See paragraph 2, page 1096, of the Dierkesmann reference.) Applicant believes the treatment disclosed in Dierkesmann is thus acute and immediate. It is not surprising that in the treatment of obstructing lesions, immediate results are desirable and vaporization is ideal. (Any remaining portion would continue to act as an obstruction in the airway.) Dierkesmann, for example, describes heating targets such as carcinomas with an intensity and wavelength sufficient to destroy and/or vaporize targets. Nothing, however, was found in Dierkesmann which teaches or suggests irradiating the walls (not obstructions) with an intensity and wavelength sufficient to cause, over time, debulking of the tissue as recited in Applicant's claims. Accordingly, Dierkesmann fails to show each of the elements (steps) required in Applicant's claims.

Based on the foregoing, reconsideration and withdrawal of the rejections of claims 33, 37, 50, and 51 under 35 U.S.C. § 102(b) as being anticipated by Dierkesmann are respectfully requested.

### **35 U.S.C. § 103(a)**

Claims 38-32, 34-36, and 38-37 stand rejected under 35 U.S.C. § 103 as being allegedly obvious over Dierkesmann in combination with Clarke et al. The Office Action states:

Dierkesmann teaches a method as claimed except the laser wavelength, discussion of spasm and discussion of the urethra and esophagus, per se. Clarke et al. teach the use of wavelengths between 300 and 1000 nm, wherein 300 nm is considered "about 240 nm" to treat obstructions in the lumens of smooth muscle organs. It would have been obvious to the artisan of ordinary skill to employ a radioactive source, since these are notorious equivalents to laser in reducing smooth muscle tissue, official notice of which is hereby taken, to employ the method on the esophagus, or urethra, since these are equivalents and both are recognized as composed of smooth muscled organs that respond to the same irradiative methods as blood vessels and bronchial tissue, official notice of which is hereby taken and to employ the method of Dierkesmann on an asthmatic lung. Since there is no indication

that such lungs are immune to the tumors Dierkesmann seeks to treat, thus producing a method such as claimed.

Applicant respectfully disagrees. The Office Action does not set forth a prima facie case of obviousness.

According to MPEP § 2142, “[t]he Examiner bears the initial burden of factually supporting a prima facie case of obviousness.” To make a prima facie case of obviousness, three requirements must be met. First, there must be some suggestion or motivation to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Third, the reference(s) must teach or suggest all the claim limitations. *Id.* at § 2143.

Here, the Office Action at least fails to teach or suggest all the claim limitations. As noted above, Dierkesmann does not show each and every limitation of the claims. Clarke fails to cure the above noted deficiencies in Dierkesmann and therefore no combination of the cited references teach or suggest each of the claim limitations. While Clarke describes an angioplasty therapy system to remove atherosclerotic plaque, Applicant could find nothing in Clarke which suggests to irradiate the walls themselves with an intensity and wavelength that causes shrinkage over time. Clarke therefore does not cure the shortcomings of Dierkesmann.

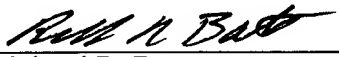
Based on the foregoing, Applicant respectfully submits that the grounds for rejection under 35 U.S.C. § 103 have been overcome and request that the rejection be withdrawn.

### III. CONCLUSION

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 435712000900. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 27, 2001

Respectfully submitted,

By:   
Richard R. Batt  
Registration No. 43,485  
Morrison & Foerster LLP  
755 Page Mill Road  
Palo Alto, California 94304-1018  
Telephone: (650) 813-5616  
Facsimile: (650) 494-0792

Attachment of Amended Claims Showing The Changes

## Attachment of Amended Claims Showing The Changes

28. (Amended) The method of claim 50 wherein [the lung is an asthmatic lung and] said irradiating step is performed by irradiating smooth muscle tissue in an asthmatic lung [comprises causing a change in smooth muscle tissue and preventing the smooth muscle tissue cells from replicating; and wherein the method further comprises controlling bronchospasms by reduction or elimination of smooth muscle tissue].

29. (Amended) The method of Claim 28, wherein [the irradiation of the walls] said irradiating step is performed by emitting a light energy having a wavelength of about 240 nm to about 280 nm.

30. (Amended) The method of Claim 28, wherein [the irradiation of the walls] said irradiating step is performed by emitting light energy having a wavelength in the red visible range.

31. (Amended) The method of Claim 28, wherein [the irradiation of the walls] said irradiating step is performed by exposing the walls to radiation emitted by a radioactive pellet.

32. (Amended) The method of Claim 28, wherein [the irradiation of the walls] said irradiating step is performed by moving an energy delivery device along the airway.

33. (Amended) A method for treating a lung comprising the step of irradiating the walls of an airway with a wavelength and intensity sufficient to cause debulking over time [The method of claim 50 wherein said irradiating step comprises causing a change] in mucus gland cells and preventing the mucus gland cells from replicating[; and wherein the method further comprises preventing mucus plugging by reduction or elimination of mucus glands].

34. The method of Claim 33, wherein [the irradiation of the walls] said irradiating step is performed by emitting a light energy having a wavelength of about 240 nm to about 280 nm.

35. The method of Claim 33, wherein [the irradiation of the walls] said irradiating step is performed by emitting light energy having a wavelength in the red visible range.

36. The method of Claim 33, wherein [the irradiation of the walls] said irradiating step is performed by exposing the walls to radiation emitted by a radioactive pellet.

37. The method of Claim 33, wherein [the irradiation of the walls] said irradiating step is performed by moving an energy delivery device along the airway.

38. The method of claim 51 wherein said irradiating step is performed by irradiating smooth muscle of [the body conduit comprises] an esophagus [and wherein said preventing step comprises preventing spasms of the smooth muscle to reduce achalasia or esophageal spasm].

39. The method of Claim 38, wherein [the irradiation of the walls] said irradiating step is performed by emitting a light energy having a wavelength of about 240 nm to about 280 nm.

40. (Amended) The method of Claim 38, wherein [the irradiation of the walls] said irradiating step is performed by emitting light energy having a wavelength in the red visible range.

41. (Amended) The method of Claim 38, wherein [the irradiation of the walls] said irradiating step is performed by exposing the walls to radiation emitted by a radioactive pellet.

42. (Amended) The method of Claim 38, wherein [the irradiation of the walls] said irradiating step is performed by moving an energy delivery device along the esophagus.

43. (Amended) The method of claim 51 wherein said irradiating step is performed on smooth muscle of [the body conduit comprises] an urethra [or an urethra and wherein said preventing step comprises preventing spasms of smooth muscle tissue to control spasms of the urethra or urethra].

44. (Amended) The method of Claim 43, wherein [the irradiation of the walls] said irradiating step is performed by emitting a light energy having a wavelength of about 240 nm to about 280 nm.

45. (Amended) The method of Claim 43, wherein [the irradiation of the walls] said irradiating step is performed by emitting light energy having a wavelength in the red visible range.

46. (Amended) The method of Claim 43, wherein [the irradiation of the walls] said irradiating step is performed by exposing the walls to radiation emitted by a radioactive pellet.

47. (Amended) The method of Claim 43, wherein [the irradiation of the walls] said irradiating step is performed by moving an energy delivery device along the urethra [or urethra].

50. (Amended) A method of treating a lung to affect lung tissue comprising:



irradiating the walls of an airway of the lung with a wavelength and intensity which, over time, causes debulking of the [causes a change in] lung tissue [cells] and prevents the lung tissue from replicating.

51. (Amended) A method of treating a body conduit having smooth muscle tissue comprising:

irradiating the walls of the body conduit with a wavelength and intensity which causes debulking of the smooth muscle tissue over time [causes a change in the cells of the smooth muscle tissue] and prevents the smooth muscle tissue from replicating and

preventing spasms of the smooth muscle tissue by [elimination or] reduction of the smooth muscle tissue over time.